

**DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR  
ADEQUATE DIRECTIONS OR WARNING STATEMENTS**

3881. Misbranding of Seconal Sodium capsules, phenobarbital tablets, capsules of pentobarbital sodium and aspirin, and methamphetamine hydrochloride tablets. U. S. v. Edward J. Lotz, Jr. (Eddie's Drug Store). Plea of nolo contendere. Fine, \$260. (F. D. C. No. 32733. Sample Nos. 16048-L to 16051-L, incl., 16053-L, 16063-L, 16064-L, 16066-L.)

INFORMATION FILED: October 16, 1952, Eastern District of Oklahoma, against Edward J. Lotz, Jr., trading as Eddie's Drug Store, Ardmore, Okla.

ALLEGED VIOLATION: On or about September 29 and October 10, 12, 15, and 16, 1951, while a number of *Seconal Sodium capsules, phenobarbital tablets, capsules of pentobarbital sodium and aspirin, and methamphetamine hydrochloride tablets* were being held for sale at Eddie's Drug Store, after shipment in interstate commerce, the defendant caused various quantities of the drugs to be repacked and dispensed without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear labels containing an accurate statement of the quantity of the contents; and Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (b) (1), the repackaged *phenobarbital tablets, capsules of pentobarbital sodium and aspirin, and methamphetamine hydrochloride tablets* failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor.

Further misbranding, Section 502 (d), the repackaged drugs, with the exception of the *methamphetamine hydrochloride tablets*, contained chemical derivatives of barbituric acid, which derivatives have been found to be, and by regulations designated as, habit forming; and the labels of these drugs failed to bear the name, and quantity or proportion of each such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (2), the repackaged *methamphetamine hydrochloride tablets* failed to bear labeling containing adequate warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form, as are necessary for the protection of users.

DISPOSITION: On December 4, 1952, the defendant filed a motion to dismiss the counts involving the dispensing of the *Seconal Sodium capsules* and entered a plea of nolo contendere to the counts charging the dispensing of the other drugs involved. On December 22, 1952, the court overruled the motion to dismiss, after which the defendant entered a plea of nolo contendere to the counts involving the *Seconal Sodium capsules*. On December 22, 1952, the court imposed a fine of \$260 against the defendant.

3882. Misbranding of Seconal Sodium capsules, tablets of phenobarbital and mannitol hexanitrate, methamphetamine hydrochloride tablets, and liquid mixture of phenobarbital and thiamine. U. S. v. James E. Martin (Martin Drug Co.). Plea of nolo contendere. Fine, \$210. (F. D. C. No. 32736. Sample Nos. 15599-L to 15602-L, incl., 15609-L, 15613-L, 15614-L.)